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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,892	07/29/2003	Lingyu Zhu	10173-084-999	5561
20583	7590	05/28/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY. 10017			MONDESI, ROBERT B	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/629,892

Applicant(s)

ZHU ET AL.

Examiner

Robert B Mondesi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 22-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's election of Invention I, Claims 16-21, in response to election of restrictions, file April 23, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### ***Priority***

The current application filed on July 29, 2003 claims priority to provisional application 60/399,928 filed on July 30, 2002.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 16-21** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims **16-21** Apolipoprotein A-I (ApoA-I) needs to be spelled out in the first instance of use.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 16-21** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The polypeptide as claimed, has an amino acid sequence duplicative of that of the non-human animal Apolipoprotein A-I (ApoA-I) protein or the cellular precursor thereof and possesses the biological and functional properties of the naturally occurring polypeptide Apolipoprotein A-I (ApoA-I) and therefore does not constitute patentable subject matter absent recitation of "isolated and purified" in the preamble.

See *American Wood v. Fiber Disintegrating Co.*, 90 U. S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U. S. 1 (1931); *Funk Brothers Seed Co. v. Kalo Inoculant*, 33 U. S. 127 (1948); and *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 17** is rejected under 35 U.S.C. 102(b) as being anticipated by Shackelford and Herbert. Shackelford and Herbert disclose a non-human animal ApoA-I protein-lipid complex comprising a non-human animal ApoA-I protein and a lipid (results, page 7176 and discussion, page 7180). Thus Shackelford and Herbert et al. teach all the elements of **claim 17** and this claim is anticipated under 35 USC 102(b).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 16 and 18-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shackelford and Herbert in view of Dasseux et al. US patent 6,037,323.

Shackelford and Herbert disclose a non-human Apolipoprotein A-I as mentioned above. Shackelford and Herbert do not disclose a pharmaceutical composition comprising a non-human ApoA-I protein lipid complex in the form of a lyophilized powder wherein the lipid is sphingomyelin. Dasseux et al. disclose a lyophilized pharmaceutical composition comprising ApoA-I agonists complexed with lipids (column 13, lines 55-66, column 45, lines 56-64) wherein the lipid is a sphingomyelin (column 46, lines 51-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to

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prepare a complex of non-human ApoA-I protein and lipid, particularly sphingomyelin, in the form of a lyophilized powder because of the benefits taught by Dasseux et al. of administration of lyophilized powders. Several lines of evidence based on data obtained in vivo implicate ApoA-1, in the prevention of atherosclerotic lesions and potentially, the regression of plaques. Animal studies further support the protective role of ApoA-I, treatment of cholesterol fed rabbits with ApoA-I reduced the development and progression of plaque. However, there are many pitfalls associated with the production and use of recombinant ApoA-I, making it is less than ideal as a drug; eg, ApoA-I is a large protein that is difficult and expensive to produce; significant manufacturing and reproducibility problems must be overcome to accomplish this goal. In view of the foregoing, there is a need for the development of alternatives to recombinant ApoA-I that mimic the activity of ApoA-I and which are relatively cost effective and simple to produce- non-human animal ApoA-I exhibiting ApoA-I activity is viable alternative to the production of recombinant ApoA-I.

### ***Conclusion***

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*RB Mondesi*  
Robert B Mondesi  
Patent Examiner  
Group 1653  
05-25-04

  
**ROBERT A. WAX**  
**PRIMARY EXAMINER**